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9	UNITED STATES DISTRICT COURT		
10	NORTHERN DISTRICT OF CALIFORNIA		
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13	EISAI INC.,	CASE NO.	
14	Plaintiff,	COMPLAINT FOR DECLARATORY JUDGMENT OF NO TRADE SECRET	
15	V.	MISAPPROPRIATION AND NO BREACH OF CONTRACT	
16	UNLEARN.AI, INC.,	DEMAND FOR JURY TRIAL	
17	Defendant.	DEMAND FOR JUNI TRIAL	
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COMPLAINT FOR DECLARATORY JUDGMENT

Case No. _____

Plaintiff Eisai Inc. ("Eisai") files this Complaint against Defendant Unlearn.AI, Inc. ("Unlearn") seeking declaratory judgment of no misappropriation of trade secrets under the Defend Trade Secrets Act ("DTSA"), 18 U.S.C. § 1836, et seq., no misappropriation of trade secrets under the California Uniform Trade Secrets Act ("CUTSA"), Cal. Civ. Code § 3426, et seq., and no breach of contract, as explained below.

THE PARTIES

- 1. Plaintiff Eisai is a Delaware corporation with offices located at 200 Metro Blvd., Nutley, NJ 07110. Eisai is a human health care company guided by the principle that patients and their families come first. Eisai's passionate commitment to patient care is the driving force behind its efforts to discover and develop innovative therapies to help address unmet medical needs, including therapies for cancer and neurological disorders, such as Alzheimer's Disease.
- 2. Unlearn is a Delaware corporation with its principal office located at 303 2nd Street, Ste. N460, San Francisco, CA 94107.

JURISDICTION AND VENUE

- 3. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 2201 and 2202 because the claims in this Complaint are based on Eisai's lack of trade secret misappropriation under the DTSA. Additionally, this Court has supplemental jurisdiction under 28 U.S.C. § 1367 over the claims for a declaratory judgment of no breach of contract and no trade secret misappropriation under the CUTSA.
- 4. The Court has personal jurisdiction over Unlearn because its headquarters and principal place of business is in San Francisco, California, and it therefore resides in this District. Unlearn also agreed to personal jurisdiction in federal courts in California in the Evaluation Agreement described below.
- 5. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) because Unlearn's headquarters and principal place of business is in San Francisco, California and it therefore resides in this judicial district. Additionally, a substantial part of the events giving rise to the claims occurred within this district.

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STATEMENT OF FACTS

- Plaintiff Eisai is a U.S.-based affiliate of Japan-based Eisai Co., Ltd. (ECL). ECL, together with Eisai and other affiliates, has decades of experience conducting and analyzing clinical trials for the development of new drugs, therapies, and treatments. Eisai's primary areas of focus are cancer and neurological disorders, including Alzheimer's Disease (AD). Over the past 40 years, Eisai has consistently pursued research and development (R&D) of drugs for dementia including AD. In 1996, Eisai's first U.S. product, Aricept[®], was approved by the U.S. Food and Drug Administration (FDA) for treatment of mild to moderate dementia of the Alzheimer's type. Recently, Eisai's unique knowledge in this field led to the development and approval of lecanemab (product name: LEQEMBI[®]), which was granted traditional approval in the U.S. in 2023 as the world's first AD treatment confirmed to slow cognitive and functional decline. On the oncology side, Eisai's Lenvima[®] is approved for treatment of certain types of thyroid cancer, renal cell carcinoma, hepatocellular carcinoma, and endometrial carcinoma, and Eisai's Halaven® is approved for treatment of certain metastatic breast cancers and unresectable or metastatic liposarcoma. Eisai currently has several ongoing Phase II, III, and IV clinical trials with a number of investigational compounds and biological agents in various stages of development. Eisai routinely uses various sophisticated statistical methodologies to support and evaluate its clinical trials.
- 7. Defendant Unlearn has stated that it is in the business of developing artificial intelligence/machine learning technologies for healthcare applications, including clinical trials.
- 8. In September 2019, the journal *Scientific Reports* published an article about Unlearn's technology titled *Machine learning for comprehensive forecasting of Alzheimer's Disease progression*. In May 2020, Eisai's investment affiliate, Eisai Innovation, Inc. (EII), and Unlearn began discussing an investment in Unlearn's Series A extension. In September 2020, Eisai invested in Unlearn.
- 9. In a press release dated November 5, 2020, Unlearn announced Eisai's investment, made through its ECL parent, in Unlearn, and further described what Unlearn called its flagship

¹ See https://www.businesswire.com/news/home/20201105005325/en/Unlearn.AI-Announces-Series-A-Extension-with-New-Investment-from-Epic-Ventures-Alumni-Ventures-Group-and-Global-Pharma-Company-Eisai.

AI-model used to generate Digital Twins that are statistically indistinguishable from actual Alzheimer's Disease patient data," and which could be used for what Unlearn called Intelligent Control Arms in clinical trials. Unlearn claimed that its Digital Twins and Intelligent Control Arms could enable smaller, more efficient clinical trials or add power to existing clinical trials. On information and belief, Unlearn was well aware of Eisai's longstanding dedication to finding ways to prevent and cure Alzheimer's Disease, and Unlearn knew that finding new and better treatments for Alzheimer's Disease was a high priority for Eisai.

- 10. Unlearn promoted its Digital Twins technology to Eisai and eventually persuaded Eisai to agree to evaluate Unlearn's Digital Twins technology. To that end, Eisai and Unlearn entered into a Mutual Confidentiality Agreement on or about November 5, 2020. The purpose of that agreement was to communicate about a potential business arrangement in which Eisai would evaluate Unlearn's Digital Twins technology using actual patient data from Eisai's previously conducted clinical trials.
- 11. After initial discussions and exchange of information under the Mutual Confidentiality Agreement, the parties next signed an Evaluation Agreement with an effective date of January 24, 2021. The purpose of the Evaluation Agreement was to give Eisai an opportunity to analyze and evaluate Unlearn's Digital Twins technology using Eisai's patient data.
- 12. In accordance with and per the terms of the Evaluation Agreement and its Statement of Work, Eisai provided Unlearn with baseline data for 300 control subjects from a clinical trial. This data was used by Unlearn to generate Digital Twins data for the 300 control subjects. Eisai compared the Digital Twins data with observed data for the 300 control subjects and was not satisfied with the prediction performance.
- 13. Unlearn then aggressively attempted to convince Eisai to enter into a new contractual engagement that would involve Eisai retaining Unlearn for additional evaluations that would involve

Digital Twins and an allegedly new statistical analysis that Unlearn referred to as prognostic

covariate adjustment (PROCOVATM), methods of which had been discussed in *Increasing the*

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efficiency of randomized trial estimates via linear adjustment for a prognostic score, an article posted by Unlearn scientists in December 2020 on arXiv.org, an open-access research-sharing platform. Unlearn sent Eisai draft proposals in August 2021 for possible collaboration on a combination of Digital Twins and PROCOVATM, but Eisai declined Unlearn's proposals given the disappointing results of the prior Digital Twins evaluation. A new engagement agreement between Eisai and Unlearn never materialized.

14. On March 15, 2022, approximately one year after Eisai had analyzed the Digital

- Twins results provided by Unlearn under the Evaluation Agreement, an Eisai scientist gave a presentation at a meeting of the Critical Path for Alzheimer's Disease (CPAD) consortium, a nonprofit, pre-competitive consortium of the Critical Path Institute (C-Path) of which Eisai is a member. The meeting was attended by, and the information was designated as confidential and only available to, CPAD consortium members. The Eisai scientist who gave the presentation has a Ph.D. in statistics and deep expertise in statistical modeling, algorithms based on machine learning and artificial intelligence, and analyses in the context of clinical trials after working in those fields for decades and publishing numerous papers in reputed journals. The Eisai scientist's CPAD presentation included a discussion of prognostic covariate analysis developed by Eisai. Following the presentation, Unlearn representatives approached the Executive Director of CPAD and accused Eisai of misusing Unlearn's intellectual property and presenting the prognostic covariate methodology as Eisai's own. The following day, Unlearn's COO, Graham Siegel, sent Dr. Shun Asami of EII an email claiming that Eisai's presentation to CPAD the day before had included information that was allegedly "essentially identical" to Unlearn's claimed proprietary PROCOVATM methodology, as published in December 2020. Mr. Siegel concluded his email by stating, "We remain eager to collaborate with Eisai's Alzheimer's Disease and other clinical programs."
- 15. Thereafter, in various communications between Unlearn representatives/counsel and Eisai representatives/counsel, Unlearn employees and outside counsel have made several claims,

shifting from asserting that Eisai presented Unlearn's published work as its own to asserting that Eisai's CPAD presentation improperly disclosed alleged Unlearn proprietary and trade secret information, in violation of confidentiality restrictions in the parties' Mutual Confidentiality Agreement and Evaluation Agreement. Eisai took seriously Unlearn's allegations about the CPAD presentation, but after studying Unlearn's allegations, Eisai determined that its CPAD presentation did not use or disclose proprietary Unlearn information or trade secrets, nor did Eisai's presentation violate any confidentiality obligations/agreements with Unlearn. Eisai has repeatedly explained that Unlearn's allegations are misguided and without merit. That is, Eisai has repeatedly explained that its CPAD presentation did not disclose any alleged trade secrets of Unlearn and did not violate any confidentiality obligations/agreements regarding Unlearn's alleged proprietary information. Such communications between the parties have included a telephone call on July 6, 2022 involving Eisai in-house counsel and Unlearn's CEO and outside counsel, a follow-up email dated August 17, 2022 from Eisai in-house counsel to the CEO and outside counsel of Unlearn, and more recent discussions between outside counsel for the parties, including an email exchange in the weeks before the filing of this complaint. Eisai's repeated attempts to resolve this dispute have not been successful.

16. The core of Unlearn's current allegations is that Eisai allegedly misappropriated trade secret and proprietary information, essentially alleging trade secret misappropriation under the DTSA and CUTSA. During discussions between parties' counsel, Unlearn's counsel proposed terms for resolution of its allegations that are completely unacceptable and unwarranted to Eisai. As a result, there exists an actual case or controversy between Eisai and Unlearn, requiring Eisai to seek a declaratory judgment of no misappropriation and no breach of the Mutual Confidentiality Agreement and Evaluation Agreement.

FIRST CLAIM FOR RELIEF (Declaratory Judgement of No Misappropriation under Defend Trade Secrets Act)

- 17. Eisai incorporates by reference the allegations contained in paragraphs 1 through 16 of this Complaint, as if fully set forth herein.
- 18. Under the DTSA, a trade secret is defined as "financial, business, scientific, technical, economic, or engineering information" that "(A) the owner thereof has taken reasonable measures to

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keep ... secret; and (B) ... derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information." 18 U.S.C. § 1839(3).

- 19. Unlearn alleges that it communicated to Eisai confidential scientific and technical information that has economic value because it can allegedly, among other things, increase the efficiency and power of clinical trials.
- 20. Under the DTSA, "misappropriation" is defined as the "(A) acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or (B) disclosure or use of a trade secret of another without express or implied consent[.]" Id. at § 1839(5).
- 21. Unlearn alleges that Eisai misappropriated Unlearn trade secret information by using and disclosing that information at the CPAD consortium meeting in March 2022 without Unlearn's express or implied consent, as explained above.
 - 22. Eisai denies Unlearn's allegations.
- 23. Eisai has not misappropriated any trade secrets under the DTSA, and Eisai has fully complied with all terms in the Mutual Confidentiality Agreement and Evaluation Agreement, including all confidentiality obligations.
- 24. Unlearn's allegations of trade secret misappropriation against Eisai, and proposed terms for resolution that Eisai finds completely unwarranted and unacceptable, have created an actual and justiciable case or controversy between Eisai and Unlearn. It is necessary and appropriate for this Court to render a judicial determination and declaration that Eisai has not misappropriated any trade secrets.

SECOND CLAIM FOR RELIEF (Declaratory Judgment of No Misappropriation under California Uniform Trade Secrets Act)

- 25. Eisai incorporates by reference the allegations contained in paragraphs 1 through 24 of this Complaint, as if fully set forth herein.
- 26. Under the CUTSA, a trade secret is defined as "information, including a formula, pattern, compilation, program, device, method, technique, or process that (1) [d]erives independent

economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and (2) [i]s the subject of efforts that are reasonable under the circumstances to maintain its secrecy." Cal. Civ. Code § 3426.1(d).

- 27. Under the CUTSA, "misappropriation" is defined as the "(1) [a]cquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or (2) [d]isclosure or use of a trade secret of another without express or implied consent by a person who: (A) [u]sed improper means to acquire knowledge of the trade secret; or (B) [a]t the time of disclosure or use, knew or had reason to know that his or her knowledge of the trade secret was: (i) [d]erived from or through a person who had utilized improper means to acquire it; (ii) [a]cquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or (iii) [d]erived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or (C) [b]efore a material change of his or her position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake." *Id.* at § 3426.1(b).
 - 28. Eisai has not misappropriated any trade secrets under the CUTSA.
- 29. Unlearn's allegations of trade secret misappropriation against Eisai, and Unlearn's proposed terms for resolution that Eisai finds completely unwarranted and unacceptable, have created an actual and justiciable case or controversy between Eisai and Unlearn. It is necessary and appropriate for this Court to render a judicial determination and declaration that Eisai has not misappropriated any trade secrets.

THIRD CLAIM FOR RELIEF (Declaratory Judgement of No Breach of Mutual Confidentiality Agreement)

- 30. Eisai incorporates by reference the allegations contained in paragraphs 1 through 29 of this Complaint, as if fully set forth herein.
- 31. Eisai has complied with all of its obligations under the Mutual Confidentiality Agreement, including its confidentiality obligations.
- 32. Unlearn's allegations of breach of the Mutual Confidentiality Agreement, and Unlearn's proposed terms for resolution that Eisai finds completely unwarranted and unacceptable,

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14	Evaluation Agreement.		
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16	WHEREFORE, Eisai respectful		
17	Unlearn as follows:		
18	A. Declare that Eisai has no		
19	DTSA and CUTSA;		
20	B. Declare that Eisai has no		
21	Evaluation Agreement;		
22	C. Deny any request by Un		
23	D. Award Eisai reasonable		
24	demands and allegations		
25	§ 1836(b)(3)(D) and Ca		
26	E. Award all further relief		
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have created an actual and justiciable case or controversy between Eisai and Unlearn. It is necessary and appropriate for this Court to render a judicial determination and declaration that Eisai has not breached the Mutual Confidentiality Agreement.

FOURTH CLAIM FOR RELIEF (Declaratory Judgement of No Breach of Evaluation Agreement)

- 33. Eisai incorporates by reference the allegations contained in paragraphs 1 through 32 of this Complaint, as if fully set forth herein.
- 34. Eisai has complied with all of its obligations under the Evaluation Agreement, including its confidentiality obligations.
- 35. Unlearn's allegations of breach of the Evaluation Agreement, and Unlearn's proposed terms for resolution that Eisai finds completely unwarranted and unacceptable, have created an actual and justiciable case or controversy between Eisai and Unlearn. It is necessary and appropriate for this Court to render a judicial determination and declaration that Eisai has not breached the Evaluation Agreement.

PRAYER FOR RELIEF

WHEREFORE, Eisai respectfully prays that the Court enter judgment in its favor and against Unlearn as follows:

- A. Declare that Eisai has not misappropriated any trade secrets of Unlearn under both the DTSA and CUTSA;
- B. Declare that Eisai has not breached the Mutual Confidentiality Agreement and the Evaluation Agreement;
- C. Deny any request by Unlearn for damages or injunctive relief;
- D. Award Eisai reasonable attorneys' fees and costs incurred in responding to Unlearn's demands and allegations of trade secret misappropriation, pursuant to 18 U.S.C.
 § 1836(b)(3)(D) and Cal. Civ. Code § 3426.4, and breach of contract;
- E. Award all further relief that the Court deems fair and just.

DEMAND TRIAL BY JURY

Eisai demands a jury trial on all matters triable by jury.

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2	Dated: June 10, 2024	FINNEGAN HENDERSON FARAROW
3	Dated. Julie 10, 2024	FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
4		By: /s/Arpita Bhattacharyya
5		By: /s/Arpita Bhattacharyya Arpita Bhattacharyya Attorneys for Plaintiff Eisai Inc.
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